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| TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110 | | | MALLARI, PATRICIA C | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|-----------------------------------|--|
| Office Action Summary | Application No. 09/813,225 | Applicant(s) ORR ET AL. | |
| | Examiner Patricia C. Mallari | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-70 and 72-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 100-109 is/are allowed.
- 6) ☒ Claim(s) 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110 and 112-115 is/are rejected.
- 7) ☒ Claim(s) 43, 46, 48-51, 61, 62, 65-69, 75, 78, 80-83, 85-87, 95-99, 111 and 116-120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. No new grounds of rejection have been presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections made under 35 U.S.C. 102 in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, 112-115 are rejected under 35 U.S.C. 102(e) as anticipated by US Patent No. 6,200,271 to Kück et al. The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Kück discloses a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient comprising a step of evaluating respiration of the patient during a first ventilation state, and a step of evaluating

respiration of the patient during a second ventilation state having a duration of about 18 to about 60 seconds (col. 9, lines 24-52; figs. 4 and 5 of Kück). The length of the duration of the “before” ventilation state is disclosed, for example, as being 6 seconds (Col. 9, lines 40-43 of Kück) or 50 seconds (figs. 4 & 5 of Kück), wherein 6 seconds is considered to be approximately 18 seconds and 50 seconds is considered to be approximately 42 seconds, particularly in reference to a time period, such as a day. The length of the duration of the “during” ventilation state is disclosed as being, for example, 50 seconds (col. 9, lines 44-52 of Kück) or 60 seconds (figs. 4 and 5 of Kück), wherein 50 seconds is considered similarly to be approximately 42 seconds and 60 seconds is considered to be approximately 42 seconds.

Regarding claim 35, the step of evaluating respiration of the patient during the first ventilation state is conducted immediately before evaluating respiration of the patient during the second ventilation state (figs. 4-5).

Regarding claim 36, the step of evaluating the patient during another first ventilation state is repeated immediately following the evaluation of respiration during the second ventilation state (col. 9, lines 52-60; figs. 4-5).

Regarding claims 37, 38, and 72, the evaluation of either of the first or second ventilation states is effected for about 30 seconds as shown in the graphs of figures 4 and 5. Note that time duration in this case, and in claims 39-41, 70, 71, 73, 74, 76, 77, and 79, the time duration cited refers to the time during which the patient's respiration is evaluated, rather than the duration of the ventilation state itself, as in claim 34.

Regarding claims 39, 40, 73, and 74, the evaluation of the patient's respiration during either of the first and second ventilation states is effected for a duration of at least about 30% of a combine duration of evaluating respiration of the patient during both the first and the second ventilation states, wherein figures 4 and 5 show that evaluation of respiration during the "before" state occurs for roughly 50 seconds, evaluation of the respiration during the "during" state occurs for roughly 60 seconds. In either case, the duration of the evaluation is at least about 30% of the combined duration of both evaluations.

Regarding claims 41 and 76, the respiration evaluation during the first and second ventilation states are effected for a combined duration of at most about two minutes (figs. 4 and 5).

Regarding claim 42, the first ventilation state comprises the patient rebreathing (col. 9, lines 44-53), wherein the "during" phase disclosed by Kück may be either the first or the second ventilation state as claimed in claim 42.

Regarding claims 44 and 45, the first ventilation state comprises the patient breathing air (col. 9, lines 32-60), where Kück shows that any gas mixture breathed by the patient constitutes "air" (col. 8, lines 51-52). With further regard to claim 45, the "before" or "after" state may be considered the second ventilation state, wherein "air" is defined as a gas mixture comprising oxygen ("air" *The American Heritage® Concise Dictionary*).

Regarding claims 47, 52-60, 63, 64, 84, 88-94, 110, and 112-115, the step of evaluating respiration of the patient is effected before calculating pulmonary capillary blood flow or cardiac output of the patient (fig. 3; col. 10, lines 45-65).

Regarding claims 52-60, 63, 64, 84, 88-94, 110, and 112-115, Kück discloses an "after" phase that constitutes the "another first ventilation state" in claim 52 of the instant application. The "after" phase of Kück has a duration of about 18 seconds to about 42 seconds, wherein figures 4-5 of Kück show the duration of the "after" phase to be about 30 seconds, and wherein the applicants describe it as lasting for 40 seconds (see p. 22 of the applicants' arguments filed 1/10/05).

With further regard to claims 53, and 54, the evaluation of respiration during each of the first, second, and another first ventilation state is effected for substantially the same duration, according to the applicants description of "substantially a same duration" on p. 12, paragraph 0048 of the instant specification. Figures 4 and 5 of Kück show the duration of the evaluation during the "before" state as being roughly 50 seconds, during the "during" state as being roughly 60 seconds, and during the "after" state as being roughly 40 seconds. Alternatively, the durations of 50, 60, and 40 seconds can be considered to be about the same, particularly in within the context of a day or a week. Note that the time limitation in this case, and in claims 55-60 and 112, differs from the limitation in claims 52 and 110, where the time duration refers to the duration of the first, second, or another ventilation state itself, rather than to the length of time during which the patient is evaluated.

With further regard to claims 55-57, the evaluation of respiration during each of the first, second, and another first ventilation states is effected for about 30 seconds, wherein the values of 40, 50, and 60 seconds are each "about 30 seconds", particularly in reference to, for example, the duration of a day.

With further regard to claims 58 and 59, the duration of the evaluation of respiration of each of the first and second ventilation states is effected for at least about 30% of a combined duration of the first and second ventilation states (figs. 4 and 5), where 50 seconds and 60 seconds each constitute at least 30% of a combined duration of 50 seconds with 60 seconds.

With further regard to claim 60, the evaluation of respiration of the patient during the first and second ventilation states are effected for a combined duration of at most 2 minutes (figs. 4 and 5).

With further regard to claims 63 and 64, the first ventilation state comprises the patient breathing air (col. 9, lines 32-60), where Kück shows that any gas mixture breathed by the patient constitutes "air" (col. 8, lines 51-52). With further regard to claim 62, the re-breathing during the "during" state of Kück may be either total or partial re-breathing (col. 4, lines 60-64 of Kück). In the instance in which partial rebreathing is effected, some portion of the gases provided for inhalation to the patient includes fresh gases, or air (col. 4, lines 1-4; col. 8, lines 48-53 of Kück) wherein air is defined as a gas mixture comprising oxygen ("air" *The American Heritage® Concise Dictionary*.)

With further regard to claims 70-74, 76, 77, and 79, Kück discloses a first phase in which a change in the effective ventilation of a patient is induced, wherein this first

phase is the time that the patient's respiration is evaluated in the "during" state of Kück, and a second phase during which a change in the effective ventilation of the patient is not present, wherein the time that the patient's respiration is evaluated in either the "before" or "after" state of Kück is this second phase (col. 9, lines 24-60). Figures 4 and 5 show these phases to have substantially the same duration according to the applicants' description of substantially the same duration on p.12, paragraph 0048 of the instant specification. Also, it is assumed that Kück, because the reference discloses a first phase in which a change in effective ventilation is induced (col. 2, lines 43-57) and a second phase during which a change in the ventilation is not present (col. 2, lines 40-43), discloses a differential Fick technique as claimed. If the inclusion of the claimed steps alone does not constitute a Fick technique as claimed by the present application, then the claim fails to include matter critical or essential to the practice of the invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph).

With further regard to claim 77, the first phase comprises a rebreathing phase ("during" col. 9, lines 43-53) and the second phase comprises a non-rebreathing phase ("before" or "after" col. 9, lines 31-43 and lines 53-60).

With further regard to claim 79, the second phase occurs before the first phase (col. 9, lines 31-52).

With regard to claims 84 and 88-94, a change in effective ventilation of a subject is induced for a first duration of time (rebreathing or "during" state) of approximately 18 to approximately 42 seconds. The change is removed for a duration of about 18 to 42 seconds immediately following the first duration of time. Measurements of at least one

respiratory gas and flow during both the first and second durations of time are obtained (col. 9, lines 32-60; figs. 4 and 5 of Kück). The length of the duration of the “during” ventilation state is disclosed as being, for example, 50 seconds (col. 9, lines 44-52 of Kück) or 60 seconds (figs. 4 and 5), wherein 50 seconds is considered similarly to be approximately 42 seconds and 60 seconds is considered to be approximately 42 seconds, particularly with reference to a day or a week. The “after” phase of Kück has a duration of about 18 seconds to about 42 seconds, wherein figures 4-5 of Kück show the duration of the “after” phase to be about 30 seconds, and wherein the applicants describe it as lasting for 40 seconds (see p. 22 of the applicants’ arguments filed 1/10/05).

Also, it is assumed that Kück, because the reference discloses all of the claimed steps recited in claim 84, the reference discloses a differential Fick technique as claimed. If the inclusion of the claimed steps alone does not constitute a Fick technique as claimed by the present application, then the claim fails to include matter critical or essential to the practice of the invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph).

With further regard to claims 88 and 112, duration of the time of inducing and the duration of removing are substantially the same, according to the applicants’ description of “substantially a same duration” on p. 12, paragraph 0048 of the instant specification. Figures 4 and 5 of Kück show the duration the “during” state, or time of inducing, as being roughly 60 seconds, and the “after” state, or time of removing as being roughly 40

seconds. Alternatively, the durations of 60 and 40 seconds can be considered to be about the same, particularly in within the context of a day or a week.

With further regard to claims 89 and 90, the duration of the evaluation of respiration of each of the first and second ventilation states is effected for at least about 30% of a combined duration of the first and second ventilation states (figs. 4 and 5), where 60 seconds and 40 seconds each constitute at least 30% of a combined duration of 60 seconds with 40 seconds.

With further regard to claim 92, the combined duration is less than two minutes (figs. 4 and 5 of Kück).

With further regard to claims 93 and 115, the inducing comprises causing the subject to rebreathe (col. 9, lines 44-52 of Kück).

With further regard to claims 94 and 114, obtaining measurements comprises obtaining measurements of carbon dioxide in respiration of the subject (col. 9, lines 6-30 of Kück).

Regarding claims 110 and 112-115, Kück discloses a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient comprising a step of evaluating respiration of the patient during a first phase in which a change in effective ventilation of the subject is induced for a first period of time (rebreathing or "during" state), and a step of evaluating respiration of the patient following removal of the change in effective ventilation of the subject (non-rebreathing or "after" state), the removal being effected for a second period of time immediately following the first (col. 9, lines 24-52; figs. 4 and 5). The length of the duration of the

"during" ventilation state is disclosed, for example, as being 60 seconds (; figs. 4, 5 of Kück), wherein 60 seconds is considered to be approximately 42 seconds, particularly with reference to a time period, such as a day. The length of the duration of the "after" ventilation state is disclosed as being, for example, 30 or 40 seconds (figs. 4 and 5) either of which values is between approximately 18 and 42 seconds.

With further regard to claim 113, evaluating respiration comprises measuring at least one respiratory gas and respiratory flow (col. 9, lines 6-30 of Kück).

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, 37-42, 44, 45, and 47 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6,106,480 to Gama De Abreu et al. Gama De Abreu teaches a method of determining cardiac output or pulmonary capillary blood flow (col. 2, lines 21-23; col. 4, line 54-col. 5, line 5) comprising a step of evaluating respiration of a patient during a first ventilation state having a duration between 18 and 42 seconds, wherein a duration of 60 seconds is about 42 seconds, and evaluating respiration of the patient during a second ventilation state having a duration between 18 and 42 seconds (col. 2, lines 40-57).

With regard to the duration of the first ventilation state, it is noted that a duration of 60

seconds is about 42 seconds, particularly in comparison to, for example, the duration of a day or a week.

Alternatively, the applicants have not disclosed that the particular range of between 18 and 42 seconds solves any stated problem or is for any particular purpose. Moreover, it appears that the method of Gama De Abreu or the applicants' invention would perform equally well with either a duration between 18 and 42 seconds or a duration of 60 seconds. In fact, the applicants disclose the range of 18 to 42 seconds as just an example of a suitable duration of either of the ventilation states (paragraph 48 of the instant application), and the specification further states that the duration of the first ventilation state may be equal to, as little as 30% of, or as much as 70% of the duration of the second ventilation state (paragraph 48 of the instant application). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use a duration of between 18 and 42 seconds as the duration of the first ventilation step in the method of Gama de Abreu because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Gama de Abreu.

Regarding claims 35, 75, figures 3 and 4 show the change between the first ventilation state and the second ventilation state as being immediate.

Regarding claims 37 and 38, the step of evaluating respiration of the patient during the first ventilation state and/or the second ventilation state is effected for about 30 seconds (col. 2, lines 40-54), wherein the ventilation state disclosed by Gama de

Abreu et al. on col. 2, lines 52-54 could be either the first or the second ventilation state as stated by the instant claim.

Regarding claims 39 and 40, the step of evaluating respiration of the patient during the first ventilation state or during the second ventilation state is effected for a duration of at least about 30% of a combined duration of evaluating respiration of the patient during both the first and second ventilation states (col. 2, lines 40-54; fig. 4), wherein a period of approximately 30 seconds or a period of between 18 and 42 seconds is at least about 30% of a duration of approximately 30 seconds combined with between 18 and 42 seconds). Similarly, a period of 60 seconds is at least about 30% of a duration of 30 seconds combined with 60 seconds. Also the ventilation state disclosed by Gama de Abreu et al. on col. 2, lines 52-54 could be either the first or the second ventilation state as stated by the instant claim.

Regarding claim 41, the step of evaluating respiration during the first ventilation state and the step of evaluating respiration during the second ventilation state are effected for a combined duration of at most about two minutes (fig. 4; col. 2, lines 40-54), wherein a duration of 30 seconds and a duration of between 18 and 42 seconds, or a duration of 30 seconds and a duration of 60 seconds combine to produce a total duration of less than two minutes.

Regarding claim 42, the step of evaluating respiration of the patient during the first ventilation state comprises evaluating respiration during rebreathing (col. 2, lines 52-54).

Regarding claims 44, the step of evaluating respiration of the patient during the second ventilation state comprises evaluating respiration of the patient while the patient is breathing air (col. 2, lines 40-51).

Regarding claim 45, the step of evaluating respiration of the patient during the second ventilation state comprises evaluating respiration of the patient while the patient is breathing gas or a gas mixture comprising at least a concentration of oxygen present in air (col. 2, lines 40-50), wherein air contains at least a concentration of oxygen (see “air”, *The American Heritage® Concise Dictionary*).

Regarding claim 47, the step of evaluating respiration of the patient during the second ventilation state is effected before calculating the pulmonary capillary blood flow of the patient (col. 4, lines 54-col. 5, line 7).

Response to Arguments

Applicant's arguments filed 12/12/05 have been fully considered but they are not persuasive.

With respect to claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 the applicants cite the definition of “approximate” as meaning “[a]most exact or correct” and “[v]ery similar; closely resembling. The applicants further submit that, under this definition, a phase lasting six seconds does not last for approximately 19 second to approximately 42 seconds, nor is a phase lasting 50 or 60 seconds within a range of approximately 18 seconds to approximately 42 seconds. However, apart from this dictionary definition, the applicants have not set forth any other

clear limitation on the term “approximately”, such as stating that the term refers to +/- 1 second or the like. As stated in the previous Office action and above, the time period of 6 seconds, 50 seconds, or 60 seconds may reasonably be considered to be very similar, closely resembling, or almost exactly to a time period of 18 seconds, particularly in the context of a timer period of a day (24 hours) or a week. Therefore, Kück *does* expressly describe a method that includes evaluating respiration during two different ventilation states that have durations of “approximately eighteen seconds to approximately forty-two seconds” as explained in the above rejection.

With regard to the rejection of claim 52, the applicants contend that Kück fails to describe evaluating respiration of the subject during *another* first ventilation state which immediately follows the second ventilation state, emphasizing that the “before” and “after” rebreathing phases of Kück are not the same. However, since the air being provided to the subject in both the “before” and “after” rebreathing phases is the same (in both, a two-way valve 68 is positioned to prevent flow of inhaled and exhaled gas through deadspace 70, see col. 9, lines 31-37 and lines 52-55 of Kück), they appear to be a same first ventilation state. Therefore, the third state of Kück and any evaluation conducted during that state is essentially a repeated first state and evaluation conducted during a first state. The applicants further cited that col. 10, lines 53-55 and 62-64 show evidence that the states are not the same. This section only shows that the results of the steps of evaluating are not the same, not that the ventilation states are not the same. If the applicants intend for the results of the evaluation to be the same, then they should amend the claim to reflect such intention clearly.

The applicants further state that even if the “after” and “before” phases of Kück were considered the same as a “first ventilation state” of claim 52, the combined rebreathing phase would have an a duration of 90 seconds rather than a duration of approximately 18 to approximately 42 seconds range. However, in neither claim 52 of the instant application nor Kück are the first and third ventilation states considered to comprise a single ventilation state. In Kück, the “before” state lasts 6 or 50 second, the “during” state 50 or 60 seconds, and the “after” state lasts 30 or 40 seconds. Again, the applicants have not provided a particular context or special definition with respect to the term “approximately”. As explained above, the term, given its dictionary definition indicates that any value very similar to, closely resembling, or almost exactly the given time period would suffice. For example, the periods of 50, 60 and 30 or 40 seconds may all be considered to be approximately, or very similar to forty-two seconds, particularly given a context of a day or a week. In a similar situation, a period of 6 seconds is considered to be approximately 18 seconds.

Claims 70 and 72-83 use the transitional phrase “consists essentially of” in the preamble. The applicants assert that Kück cannot anticipate claim 70 because the reference is limited to a rebreathing technique that includes three distinct phases and the method of claim 70 consists essentially of a first and second phase. However, the applicants’ specification, as well as claim 75, shows that the applicants’ method is not limited to merely a first and a second phase, but that the first and second phases may be repeated. This information, among other things, indicates that there is no clear indication of what the basic and novel characteristics of the invention are. Absent such

an indication, “consisting essentially of” is construed to mean “comprising.” See MPEP §2111.03. Furthermore, as explained above, Kück teaches a differential Fick technique comprising a first and second phase as claimed, wherein the “third phase” is merely a repeat of a first phase. Therefore, Kück does anticipate claims 70 and 72-83 as set forth in the rejection above.

With regard to the rejection of claim 36, the applicants further contend that the Kück does not expressly or inherently describe repeating evaluating respiration of the subject during another first ventilation state *immediately following* evaluating respiration of the subject during a second ventilation state and instead teaches evaluating respiration of a subject during a first, second, and third state, before repeating. Both the first and third states of Kück are non-rebreathing states or states in which a two-way valve 68 is positioned to prevent flow of inhaled and exhaled gas through deadspace 70 (col. 9, lines 31-37 and lines 52-55 of Kück). Therefore, the third state of Kück and any evaluation conducted during that state is essentially a repeated first state and evaluation conducted during a first state. Figures 4 and 5 of Kück show no interruption between evaluation during the second and evaluation during the third state (“during” and “after” respectively), nor does the specification indicate any interruption between the two states. In fact, Kück states, “After re-breathing, two-way valve 68 is repositioned to prevent the flow of gases through deadspace 70 as the patient breathes” (col. 9, lines 53-54 of Kück). The third state, or repeated first state, is effected without delay following the second state. Thus, Kück teaches a method in which respiration is

evaluated immediately following evaluating respiration of the subject during the second ventilation state.

With regard to claim 45, the applicants contend that Kück does not describe evaluating respiration of a subject during a second ventilation state in which the subject breathes a gas or gas mixture comprising at least a concentration of oxygen present in air". As stated in the above rejection, the "before" state may be considered the second state, and the subject is provided air in the second state, wherein "air" is defined to be a gas mixture comprising oxygen.

With regard to claims 53 and 54, the applicants state that Kück fails to disclose the first and second ventilation state being effected for substantially a same duration and/or the another first ventilation state being effected for substantially the same duration. As stated in the previous Office action and in the rejection above, Figures 4 and 5 of Kück show the duration of the evaluation during the "before" state as being roughly 50 seconds, during the "during" state as being roughly 60 seconds, and during the "after" state as being roughly 40 seconds. The durations of 50, 60, and 40 seconds can be considered to be about or substantially the same, particularly within the context of a day or a week.

With regard to claims 55-57 and 72, the applicants state that neither of the values 6, 50, or 60 seconds is "even close to 30 seconds". However, claims 55-57 recite that the various states are effected for "about 30 seconds". As with the term "approximately", the applicants have not provided a particular context or special definition with respect to the term "about". Given the term's broadest reasonable

interpretation, the term indicates that any value similar to the given time period would suffice. For example, the periods of 6, 50, 60, or 40 are considered to be "about" 30 seconds, particularly given a context of a day or a week.

The applicants argue that Kück fails to teach a second ventilation state in which the patient breathes gas or a mixture comprising at least a concentration of oxygen present in air as recited in claim 64. As explained in the above rejection, the rebreathing state of Kück may utilize partial rebreathing, in which case fresh air is supplied to the patient, air being a gas mixture that comprises oxygen.

The applicants also argue that Kück fails to teach a first and second duration of time that are substantially the same, as recited in claim 88. The above rejection addresses how Kück shows such durations to be substantially the same.

The applicants contend that Kück fails to teach a change in effective ventilation may be induced for about thirty seconds and removed for about thirty seconds as claimed in claim 91. See the rejection above as to how Kück teaches the method of claim 91.

Again, with respect to the applicants' argument that the duration of the "during" state of Kück is well outside of the approximately 18 to approximately 42 seconds range, the applicants have not provided a particular context or special definition with respect to the term "approximately". Given the term's definition, the term indicates that any value very similar to, closely resembling, or almost exactly the given time period would suffice. For example, given a period of a day (24 hours) or a week, the time period of 50 or 60 seconds is considered to be similar to a time period of 42 seconds.

Art Unit: 3736

Therefore, the rejections of claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 as being anticipated by Kück stand.

With respect to the rejection of claims as being anticipated by or in the alternative being unpatentable over Gama De Abreu, the applicants argue that the sixty-second rebreathing period of the reference is not approximately 18 seconds to approximately 42 seconds, in length. See the above explanation of how a 60 second period is reasonably considered to be approximately 42 seconds. Therefore, Gama de Abreu indeed discloses the method recited in claim 34 of the instant application.

With regard to a 103 rejection of claims as being unpatentable over Gama de Abreu, the applicants state that the assumption by the Office that a nonrebreathing period having a duration of less than 60 seconds would perform equally well does not amount to a motivation or suggestion to one of ordinary skill in the art to modify the teachings of Gama de Abreu. As stated in the above rejection and in the previous Office actions, the motivation or suggestion generally available to one of ordinary skill in the art and in light of the disclosure of the prior art is that of mere design choice, since the applicants have not shown that the recited durations solve any stated problem or is for any particular purpose. That it appears the duration of less than 60 seconds would perform equally well is merely support for showing that the motivation is mere design choice. (See the above rejection for further explanation of such motivation.) It is further noted that the applicants have not shown otherwise.

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Therefore, the rejection of claims 34, 35, 37-42, 44, 45, and 47 as being anticipated under 35 U.S.C. 102(e) or alternatively unpatentable under 35 U.S.C. 103(a) over Gama de Abreu stands.

Allowable Subject Matter

Claims 100-109 are allowed. Claims 43, 46, 48-51, 61, 62, 65-69, 75, 78, 80-83, 85-87, 95-99, 111, and 116-120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of claims 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-109, 111, and 116-120 were addressed in a previous Office action filed 3/4/04. The allowability of claims 43 and 75 were addressed in a previous Office action filed 4/5/05.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PC
Patricia Mallari
Patent Examiner
Art Unit 3736

McHendry
[Stamp: RECEIVED, 10/2/2009, 10:00 AM, 3736]